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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/582,808 | 10/16/2000 | Ib Mendel-Hartvig | | 2872 |

7590 04/07/2003

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| EXAMINER | |
|---|---|
| COUNTS, GARY W | |
| **ART UNIT** | **PAPER NUMBER** |
| 1641 | 14 |

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Advisory Action | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/582,808 | MENDEL-HARTVIG ET AL. | |
| | Examiner | Art Unit | |
| | Gary W. Counts | 1641 | |

*--Th MAILING DATE of this communication app ars on the cover she t with the correspondenc address --*

THE REPLY FILED 25 February 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attachment*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *42-83*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Gary Counts

Gary W. Counts
Examiner
Art Unit: 1641

## DETAILED ACTION

### Attachment to Advisory Action

1. Continuation of NOTE 5: Applicant argues that Charlton does not teach immobilized particles exhibiting hydrophilic groups on their surface. Applicant states the disadvantages of the hydrophobic features of Charlton particles. This argument has been fully considered but is not persuasive because these arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the Examiner has not relied upon Charlton for the hydrophobic particles but has relied upon Porrvik for hydrophilic particles and the specific teaching that the Porrvik particles can be used in solid phase immunoassays (col 1, lines 8-15).

Applicant further argues that Porrvik does not teach that the particles manufactured according to her method are suitable for use in a flow matrix or may be anchored to a flow matrix by such immobilized particles. This is not persuasive because Porrvik specifically teaches that the hydrophilic particles can be used as a solid phase in heterogenic immunoassay (col 1, lines 14-15) (i.e. the assay of Charlton). And it would have been obvious to one of ordinary skill in the art that the hydrophilic particle of Porrvik would be an obvious variation of a solid phase that uses hydrophilic groups.

Applicant argues that Charlton does not teach or suggest porous particles or any reaction kinetics dependent on porous particles. Applicant also argues that the flow

through the porous particles **may** undesirably result in capture of detection conjugate in the pores. This argument is irrelevant because Charlton nor the instantly recited claims have excluded the use of porous particles. Further, Charlton specifically teaches that these particles can be used as solid phases in heterogenous immunoassays (col 1, lines 14-15) (i.e. the assay of Charlton). It is also well know in the art that hydrophilic carriers provide the advantage of reducing non-specific binding to the carrier.

Applicant argues that the tertiary reference Devlin, does not teach or suggest a method or test kit employing a flow matrix as presently claimed wherein an analytically detectable group reactant has labeled particles as an analytically detectable group and a biospecific affinity reactant is anchored to the flow matrix via immobilized particles exhibiting hydrophilic groups on their surface. This is not found persuasive because Examiner has not relied upon the tertiary reference for these limitations. The above listed limitations are taught by the combination of the primary and secondary references. Examiner has relied upon Devlin for the detection of allergens by immunoassay which are well known in the art.

Applicant argues that the tertiary reference Dafforn, does not teach or suggest a method or test kit employing a flow matrix as presently claimed wherein an analytically detectable group reactant has labeled particles as an analytically detectable group and a biospecific affinity reactant is anchored to the flow matrix via immobilized particles exhibiting hydrophilic groups on their surface. This is not found persuasive because Examiner has not relied upon the tertiary reference for these limitations. The above limitations are taught by the combination of the primary and secondary references.

Examiner has relied upon Dafforn for the application of reagents upstream of a sample applicant and the advantages of this type of application (see previous office action).

Applicant argues that the tertiary reference Brown does not teach or suggest a method or test kit employing a flow matrix as presently claimed wherein an analytically detectable group reactant has labeled particles as an analytically detectable group and a biospecific affinity reactant is anchored to the flow matrix via immobilized particles exhibiting hydrophilic groups on their surface. This is not found persuasive because Examiner has not relied upon the tertiary reference for these limitations. The above limitations are taught by the combination of the primary and secondary references. Examiner has relied upon Brown for teaching the advantages that the particles anchoring the capturer have a size, which is smaller than a smallest inner dimension of the flow channels of the matrix (see previous office action for advantages).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
March 13, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
03/29/03